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EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 10-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The newly amended limitation of determining validity “after the collection of each individual one of the second selected events” is lacking support at the cited portion of the specification (pg. 22, lines 1-6). This passage refers to Figure 6, which shows determining validity at block 540, but only after the collection of the entire set of second selected events (at 522), not each individual event.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Kim et al. (US 2002/0183637, hereinafter “Kim”).

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5. In regards to claims 1 and 10, Kim discloses a device/method for generating a template of a normal heartbeat comprising detecting a plurality of heartbeats (par. 0007-0010), collecting a first predetermined number of detected non-paced heartbeats having predetermined characteristics (via Figs. 4 and 6), generating a current template from the first selected events, waiting a predetermined delay (par. 0064), collecting a second predetermined number of detected non-paced heartbeats, then determining whether the template is valid based on a comparison of the collected second selected events with the current template (Fig. 6, “If a Template exists, correlate it with the next 21 template beats” block; and par. 0082-0083), and generating an updated template if the current template is not valid (par. 0010 and Fig. 6) from the collected second beats (Fig. 6; “If not correlated” path). Please note that, although an embodiment utilizes paced and non-paced beats to determine “regularity”, these paced beats are not used for template generation, per the rules of paragraph 0078 and 0081. Further, Kim discloses an embodiment without therapy provision per paragraphs 0065 (“monitor mode”) and 0041 (“only monitoring of cardiac activity is performed”). As such, all beats are inherently non-paced because no pacing therapy is provided. Regarding claim 10’s limitation of determining validity “based upon” a comparison after the collection of each individual one of the second events, please see paragraph 0082’s discussion of comparing on a beat-by-beat basis.

6. In regards to claims 2 and 11, the template update is repeated (par. 0064).

7. In regards to claims 3 and 12, identifying events as first selected events comprises determining whether consecutive events have a first characteristic (i.e.

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comprise the first 20 beats) and identifying a predetermined number of subsequent events as second selected events (i.e. comprise the beats subsequent to the 20 beats).

8. In regards to claims 4 and 13, the “monitoring only” embodiment requires that consecutive events have an RR-interval greater than a threshold per paragraph 0071. Further, the “NSR” beats of paragraphs 0078-0081 are consecutive to each other (although they may or may not be consecutive with respect to all heart beats) and have RR-intervals greater than a threshold because they must pass the “regularity” test of 0071.

9. In regards to claims 7, 8, 16 and 17, a cross-match is determined and compared to a threshold and a delay is generated if the threshold comparison fails (par. 0108).

10. In regards to claims 9 and 18, R-R intervals associated with the first events are compared to an average (par. 0071); a cross-match is computed (par. 0105) if the R-R intervals are greater (or less) than the average; and a template is generated from the events corresponding to the cross-matches (par. 0108).

11. In regards to claims 5, 6, 14, 15, and 19, Kim discloses that valid sense events having first and second characteristics comprise the following characteristics: the sense event is not a ventricular pace event (par. 0078), the event has an R-R interval greater than a predetermined rate of about 600 ms (par. 0071), the sense event can comprise events other than those directly following a ventricular pace (par. 0078), and the ventricular sense event follows an atrial pace event by a predetermined threshold (par. 0081, rule 5) and is about 100 ms (see Fig. 9, $\frac{1}{2}$ of the 320 ms window is the threshold).

Response to Arguments

12. Applicant's arguments filed 11/11/2008 have been fully considered but they are not persuasive. Applicant argued that Kim does not disclose that multiple beats are stored because analysis is conducted on a beat-by-beat basis, thus Kim does not disclose collecting the second selected events and then determining whether the current template is valid. Ostensibly, it appears that the limitations of claims 1 and 10 are mutually exclusive inasmuch as the determination of validity of the current template cannot be based on both a comparison of the second selected events (plural) with the current template after the collection of the second selected events (as in claim 1) and after the collection of each individual one of the second selected events (as in claim 10). However, the claim language only requires that the determination of validity be "based on" a comparison of the second selected events with the current template after the collection of the second selected events (as in claim 1) and after the collection of each individual one of the second selected events (as in claim 10). Kim discloses that determination of validity comprises comparing the newly detected beats on a beat-by-beat basis (par. 0082), and that a determination of validity is also based on a certain number of the total set being correlated or not correlated (par. 0083). In other words, the beats are collected and compared on a beat-by-beat basis, but "determining whether the current template is valid" (per paragraph 0083) is performed after the potential template beats have been collected. Regardless of whether the "comparison" step occurs after the collection of the second selected events, the "determining" step does occur after the "collecting" step (par. 0083). As the claim language does not

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require that the “comparison” occurs after “collecting” (but only that the “determining” is “based upon” this comparison), the examiner maintains the position that Kim reads on the claim language.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **MICHAEL KAHELIN** whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Kahelin/
Examiner, Art Unit 3762

/Angela D Sykes/
Supervisory Patent Examiner, Art Unit 3762